Telix Launches New Prostate Cancer Imaging Agent, Gozellix, in U.S.

11 Jun 2025

MELBOURNE, Australia and INDIANAPOLIS, June 11, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix", "the Company") today announces that its next-generation PSMA-PET imaging [1] agent for prostate cancer, Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), is now commercially available nationally in the United States (U.S.).

Gozellix is available through Telix's comprehensive network of distribution partners, Cardinal Health, Inc., PharmaLogic Holdings Corp., Jubilant Radiopharma, and RLS Radiopharmacies.

After radiolabelling with ^{68}Ga, Gozellix is indicated for PET[2] scanning of PSMA[3] positive lesions in men with prostate cancer who have suspected metastasis and are candidates for initial definitive therapy, and those with suspected biochemical recurrence (BCR) based on elevated serum prostate-specific antigen (PSA) level. Gozellix builds on proven diagnostic excellence to provide early and accurate detection of metastases at initial staging, with 90% specificity[4]. This clinical performance enables detection of millimetre-scale micrometastases, at PSA levels as low as 0.02 ng/mL[5]. These valuable insights enable physicians to make more informed clinical decisions.

In recent years, PSMA-PET imaging has become established as the standard of care for staging and identifying biochemical recurrence of prostate cancer[6]. However, only a relatively small fraction of the 3.4 million men living with prostate cancer in the U.S. have benefited from this technology, in part due to access and availability challenges[7,8]. Telix has applied for reimbursement for Gozellix, for Medicare-eligible patients in the hospital outpatient setting[9,10].

Gozellix's enhanced formulation, with an extended "hot" shelf-life of up to six hours, offers a greater level of patient access and convenience through an extended transportation distance and clinical administration window. Telix estimates that up to 20% of PET cameras in the U.S. are beyond the reach of currently available PSMA-PET imaging agents due to distribution efficiency constraints[11]. By overcoming this limitation, Gozellix can improve access for prostate cancer patients, regardless of where they live, with greater scheduling flexibility for clinicians and their patients.

Gozellix can be either centrally produced with a cyclotron or locally prepared with a gallium generator with up to 500mCi of activity, enabling greater production flexibility and on-demand capacity. Cyclotron-based production of Gozellix is supported by the ARTMS QUANTM Irradiation System® (QIS®), the market-leading cyclotron solid target irradiation system[12].

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, said, "We are pleased that Gozellix, our next-generation prostate cancer imaging product, is now available coast-to-coast across the United States. Telix is committed to innovation in PSMA imaging, and Gozellix is a result of this focus. It delivers a new level of flexibility in distribution, production and scheduling, along with the high standard of service and reliability that customers have come to expect from Telix."

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Brazil, Canada, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. ARTMS, IsoTherapeutics, Lightpoint, Optimal Tracers and RLS are Telix Group companies. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Illuccix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved by the U.S. FDA[13], by the Australian Therapeutic Goods Administration (TGA)[14], by Health Canada[15], by the Brazilian Health Regulatory Agency (ANVISA)[16], by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)[17], by the French National Agency for the Safety of Medicine and Health Products (ANSM), by the German Federal Institute for Drugs and Medical Devices (BfArM), and in multiple other countries within the European Economic Area (EEA) following a positive decentralized procedure (DCP) opinion by the German medical regulator. Gozellix (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA[18].

ARTMS is a Telix company, and its core technology platform is the QUANTM Irradiation System® (QIS®): a complete cyclotron-based isotope production system designed to support high efficiency, large-scale and cost-effective production of commercially important medical isotopes.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, ASX and SEC filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on LinkedIn, X and Facebook.

Telix Investor Relations

Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Investor Relations and Corporate Communications
Email: kyahn.williamson@telixpharma.com

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Risk for Misinterpretation
Image interpretation errors can occur with Gozellix PET. A negative image does not rule out the presence of prostate cancer, and a positive image does not confirm the presence of prostate cancer. Gallium Ga-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include

histopathological evaluation of the suspected prostate cancer site, is recommended.

Imaging Prior to Initial Definitive or Suspected Recurrence Therapy
The performance of Gozellix for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of Gozellix for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

Radiation Risks
Gallium Ga-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration.

Hypersensitivity Reactions
Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

ADVERSE REACTIONS
The safety of gallium Ga-68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMABCR studies, each receiving one dose of gallium Ga-68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

DRUG INTERACTIONS
Androgen deprivation therapy and other therapies targeting the androgen pathway Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga-68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga-68 gozetotide PET has not been established.

Please note that this information summary is not comprehensive.

Please see the Full Prescribing Information here.

You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report adverse reactions to Telix Pharmaceuticals (US) by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

Legal Notices

You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.

The information contained in this announcement is not intended to be an offer for subscription, invitation or recommendation with respect to securities of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United States. The information and opinions contained in this announcement are subject to change without notification. To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to update or revise any information or opinions contained in this announcement, including any forward-looking statements (as referred to below), whether as a result of new information, future developments, a change in expectations or assumptions, or otherwise. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this announcement.

This announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as "may", "expect", "intend", "plan", "estimate", "anticipate", "believe", "outlook", "forecast" and "guidance", or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix's product candidates, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix's product candidates, if or when they have been approved; Telix's ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix's business; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.

©2025 Telix Pharmaceuticals Limited. Telix Pharmaceuticals, Telix Group company, and Telix product names and logos are trademarks of Telix Pharmaceuticals Limited and its affiliates – all rights reserved. Trademark registration status may vary from country to country.

[1] Imaging of prostate-specific membrane antigen with positron emission tomography.

[2] Positron emission tomography.

[3] Prostate-specific membrane antigen.

[4] PSMA-PreRP clinical study. ClinicalTrials.gov ID: NCT02919111.

[5] Giesel et al. *Eur J Nucl Med Mol Imaging*. 2015; Alipour et al. *Ther Adv Med Oncol.* 2019; Burgard et al. *Cancers (Basel).* 2023 and Abghari-Gerst et al. *J Nucl Med.* 2022.

[6] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2025

[7] NIH Common Cancer Sites — Cancer Stat Facts. Accessed May 2024.

[8] Company analysis based on proprietary and public domain data.

[9] Hospital Outpatient Prospective Payment System (HOPPS) patients eligible for reimbursed PSMA-PET scanning.

[10] Telix has applied for a unique HCPCS code for Gozellix and will also pursue Transitional Pass-through status with Center for Medicare and Medicaid Services (CMS).

[11] Data on File. Distribution Metrics. Telix Pharmaceuticals. 2023.
[12] Type II DMF for gallium-68 chloride - DMF# 035947
[13] Telix ASX disclosure 20 December 2021.
[14] Telix ASX disclosure 2 November 2021.
[15] Telix ASX disclosure 14 October 2022.
[16] Telix ASX disclosure 18 March 2025.
[17] Telix ASX disclosure 13 February 2025.
[18] Telix ASX disclosure 21 March 2025.